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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte THOMAS W. DAVISON

Appeal 2009-014681
Application 10/689,487
Technology Center 3700

Before TONI R. SCHEINER, DONALD E. ADAMS, and STEPHEN
WALSH, *Administrative Patent Judges*.

WALSH, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134(a) involving claims to a system for performing a spinal fixation. The Patent Examiner rejected the claims on the ground of obviousness. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

STATEMENT OF THE CASE

Claims 18-23, 25-27, 30-36, 38-41 and 46-48, which are all the pending claims, are on appeal. Claim 18 illustrates the subject matter and reads as follows:

18. A system for performing a fixation procedure at a spinal location within a patient, comprising:
at least two fasteners adapted to be fixed to two adjacent vertebrae;
an elongate body having a proximal end and a distal end and defining a length between the proximal and distal ends such that the proximal end can be positioned outside the patient and the distal end can be positioned inside the patient adjacent the spinal location, the elongate body including a passage extending between the proximal and distal ends sized to permit passage of the at least two fasteners therethrough; and
a fixation element sized to pass through the passage of the elongate body and configured to engage the at least two fasteners;
wherein the elongate body is actuatable between a first configuration sized for insertion into the patient and a second configuration wherein the cross-sectional area of said passage at a first location is greater than the cross-sectional area of said passage at a second location, wherein the first location is distal to the second location; wherein the cross-sectional area of said passage at said first location is sized to permit visualization of two fasteners fixed to two adjacent vertebrae.

The Examiner rejected all the claims under 35 U.S.C. § 103(a) as unpatentable over Foley,¹ Ash,² and Zdeblick.³

¹ Kevin Thomas Foley et al., US 5,792,044, issued Aug. 11, 1998.

² Stephen R. Ash et al., WO 83/03189, published Sept. 29, 1983.

³ Thomas Zdeblick et al. US 6,206,922 B1, issued Mar. 27, 2001.

OBVIOUSNESS

The Issues

The Examiner's position is that Foley described a system comprising an elongate body usable with at least two fasteners, a viewing element, and an access path between proximal and distal ends. (Ans. 3, citing Foley at col. 15, ll. 3-20, and col. 5, ll. 51-65.) The Examiner found that Foley did not disclose a system comprising (1) an elongate body expandable at the distal end, and (2) a fixation element with at least two fasteners capable of being passed through the elongate body. (*Id.*) According to the Examiner, Ash taught a device comprising an elongate body expandable at the distal end in order to provide viewing and operation room (*id.*, citing Ash 2, ll. 24-35), and the Examiner concluded it would have been obvious to manufacture Foley's device with an expandable distal end in order to provide viewing and operation room (*id.* at 4). The Examiner further found that Zdeblick taught a system comprising a fixation element capable of being passed through the passage of an elongate body in order to fuse two adjacent vertebrae, and the Examiner concluded it would have been obvious to manufacture Foley's device "comprising a fixation element with at least two fasteners capable of being passed through the passage of an elongate element in view of Zdeblick in order to . . . fuse two adjacent vertebrae." (*Id.* at 3-4.) The Examiner further explained why claims 18, 27, 33, and the remaining claims would have been obvious, citing additionally Zdeblick's Fig. 10. (*Id.* at 4-5.)

Appellant first contends that the Examiner misinterpreted or ignored the structure of the "fixation element . . . configured to engage the at least two fasteners" (claim 18), and the structure of the "fastener adapted to

engage each of the vertebral screws” (claim 27). (App. Br. 6-7) More specifically, Appellant contends that “while Zdeblick does appear to teach implants for fusing adjacent vertebrae, the reference does not appear to teach a fixation element configured to engage two fasteners, as is recited in claim 18, or a fastener adapted to engage vertebral screws as recited in claim 27.” (*Id.* at 7.) In Appellant’s view, Zdeblick is “irrelevant because the claimed system does not recite for fusing vertebrae, but rather a fixation system configured to engage two fasteners (claim 18) or a fastener adapted to engage vertebral screws (claim 27).” (*Id.*)

Appellant next contends that (a) “[t]he Examiner’s reasons for combining Foley, Ash, and Zdeblick are contradicted by the references themselves” (*id.* at 7-9); (b) “the Examiner has failed to provide any objective reason with rational underpinning to combine the teachings of Foley, Zdeblick and Ash” (*id.* at 9); (c) combining the references would not have provided “predictable results” (*id.* at 10); (d) the combined teachings at best would have resulted in a fusion implant, not the claimed system (*id.* at 11); and (e) “Foley actually appears to teach away from modifications to their system using Ash” (*id.* at 12); .

The Examiner responds that vertebral screws and a fixation element were described by Zdeblick’s elements 350 and 366, “wherein the vertebral fixation assembly is passed through an access device and fixes, i.e. fuses, two adjacent vertebrae as required by the claims.” (Ans. 5-6.) The Examiner further responds that Ash was relied on as suggesting an improvement to prior art devices such as Foley’s, and explains why Appellant’s argument that the suggested modification would not have provided predictable results was unpersuasive. (*Id.* at 6-7.)

Appellant disagrees that Zdeblick's Fig. 35 fusion device is a vertebra screw (Reply Br. 1), and maintains the argument that there was no motivation to attempt placing Zdeblick's device through a modified cannula suggested by Foley and Ash. According to Appellant, Zdeblick and Foley taught placing the first device, then unseating the laparoscope and placing the second device, or using two endoscopes. (*Id.* at 2.) According to Appellant, the claimed system must accommodate simultaneous passage of a fixation element and fasteners. (*Id.* at 3.)

The issues are:

whether the Examiner reasonably interpreted the "fixation element" and "fasteners," "vertebral fixation assembly," and "vertebral screws" of claims 18, 27, and 33, as reading on Zdeblick's fusion devices and screws;

whether the evidence supports the Examiner's finding that Ash suggested making Foley's device expandable at the distal end;

whether the evidence supports the Examiner's finding that Zdeblick suggested a system wherein Zdeblick's fusion devices and screws could be passed through Foley's modified device;

whether the teachings of the references were properly and predictably combinable; and

whether the preponderance of the evidence supports the Examiner's conclusion of obviousness.

Findings of Fact

1. Zdeblick's Fig. 10 is reproduced here:

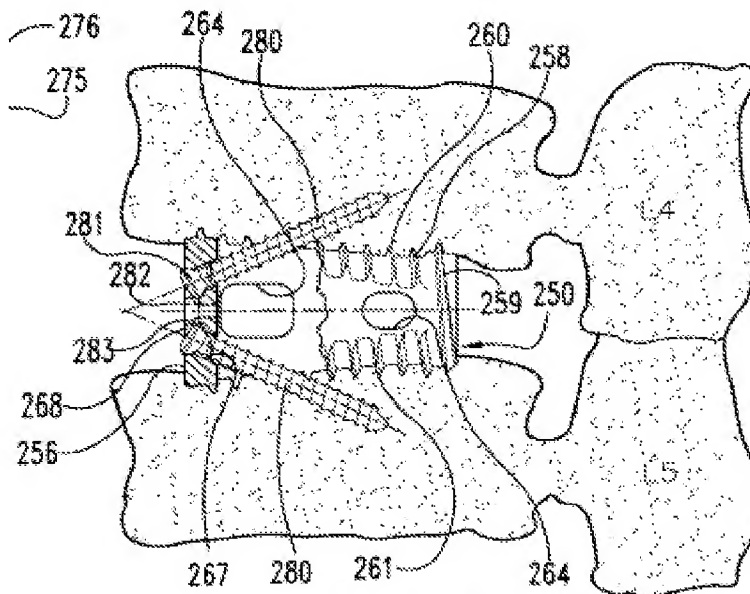


Fig. 10

{“FIG. 10 is a side partial cross-sectional view of a fusion device . . . disposed between adjacent vertebrae and engaged in position by a pair of bone screws” (Zdeblick, col. 5, ll. 46-50.)}

2. Zdeblick teaches:

The driving tool attachment 275 can be engaged to a fusion device, such as device 250, to permit threading of the device into the intervertebral disc space, such as the space between lumbar vertebrae L4 and L5, as shown in FIG. 10.

With the fusion device 250 appropriate [sic] positioned within the intervertebral disc space, a pair of bone screws 280 can be extended through respective screw bores 267 in the hollow body 251. The screws are passed through the bores 267 until the bone engaging threads of the screws 280 contact the vertebral bone.

(Zdeblick, col. 10, ll. 28-36.)

3. Zdeblick’s Fig. 35 is reproduced here:

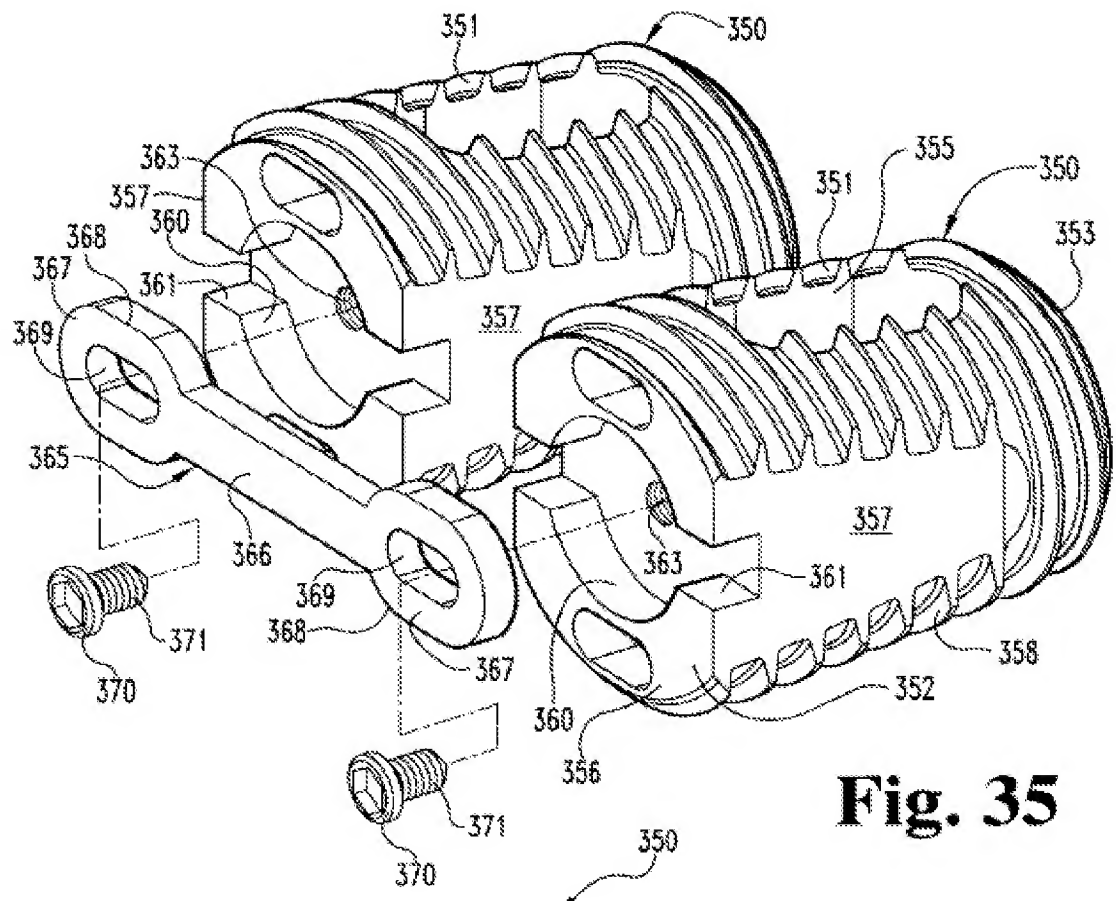


Fig. 35

{“FIG. 35 is a side perspective view of an assembly . . . utilizing a pair of fusion devices connected by a connector plate. (Zdeblick, col. 7, ll. 6-9.)}

4. Zdeblick teaches:

Another approach is presented in FIGS. 35-36. In this approach, bilaterally placed fusion devices are connected laterally across the disc space, thereby preventing each device from rotating. In a first embodiment shown in FIG. 35, a pair of fusion devices 350 are provided that include a hollow body 351 having a first end 352 and a second end 353. As with the fusion devices previously discussed, the devices 350 each include a hollow interior 355 and an end wall 356. The devices also include external threads 358 that are adapted to be threaded into a prepared bore in adjacent vertebrae.

(Zdeblick, col. 24, ll. 25-35.)

Principles of Law

A rejection for obviousness must include “articulated reasoning with some rational underpinning to support the legal conclusion.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007), quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006). The criterion for combining prior art teachings is “not whether the references could be physically combined but whether the claimed inventions are rendered obvious by the teachings of the prior art as a whole.” *In re Etter*, 756 F.2d 852, 859-60 (Fed. Cir. 1985) (*in banc*) (citations omitted). A warning against use of an element, rather than omission of mention of the element, is required to find teaching away. *Para-Ordnance Manufacturing v. SGS Importers International Inc.*, 73 F.3d 1085, 1090 (Fed Cir. 1995). “Absent claim language carrying a narrow meaning, the PTO should only limit the claim based on the specification or prosecution history when those sources expressly disclaim the broader definition.” *In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004).

Analysis

1. As to claim 18, we agree with the Examiner that Zdeblick's fusion device is a fixation element, and that because Zdeblick showed the fusion device engaged with two vertebral screws in Fig. 10 (see FF1), Zdeblick described a "fixation element" "configured to engage [] at least two fasteners." We agree with the Examiner's explanation that the fusion device "fixes, i.e. fuses" adjacent vertebrae and is therefore properly considered a fixation element. (Ans. 5-6.)

As to claim 27, we again agree that Zdeblick's Fig. 10 showed a "vertebral fixation assembly configured to fix two adjacent vertebrae," the assembly comprising a "plurality of vertebral screws and a fastener adapted to engage each of the vertebral screws," because Zdeblick's fusion device itself is the claimed "fastener adapted to engage each of the vertebral screws." The fusion device functions as a fastener in two senses: it fixes or fastens adjacent vertebrae, and it fastens the vertebral screws.

As to claim 33, Zdeblick showed "at least two threaded fasteners" in Fig. 35. (See FF3.) Zdeblick described devices 350 in Fig. 35 as threaded (FF4), and showed them "configured to be fixed to adjacent vertebrae." Fig. 35 showed device 366, corresponding to the claimed "fixation element."

Appellant's argument seems to assume specialized meanings for such general terms as fastener, vertebral screw, and fixation element. However, Appellant has not shown a basis for limited, narrow meanings in the Specification. We conclude that the Examiner reasonably interpreted the "fixation element" and "fasteners," "vertebral fixation assembly," and "vertebral screws" of claims 18, 27, and 33, as reading on Zdeblick's fusion devices and screws illustrated in Figs. 10 and 35.

2. Appellant and the Examiner have discussed the spinal surgery disclosures in all three prior art references. Although Appellant disputes that the references were properly combined, we find as a preliminary matter that the references were all in the same field of endeavor and were appropriate sources of suggestions for modifying each other's systems and methods.

The Examiner found, and we agree, that Ash disclosed viewing advantages when a surgical device for internal operations is equipped with an expandable distal end. We also agree that the Examiner's evidence supports finding that Ash's disclosure suggested a like modification to Foley's device. Although Appellant argues there would be no need to improve Foley's device with an expanded field of view, we think the Examiner's position makes more sense.

3. We agree with the Examiner's finding that Zdeblick suggested a system wherein Zdeblick's fusion devices and screws could be passed through Foley's modified device.

4. According to Appellant, Foley and Zdeblick teach sequential placement of implants, which Appellant takes as a teaching away from a system that can accommodate simultaneously passing a fixation element and two fasteners (claim 18), or a plurality of screws and a fastener (claim 27), or two threaded fasteners and a fixation device (claim 33). Assuming that Foley and Zdeblick did teach sequential placement of implants, we are not persuaded that a person of ordinary skill in the art would have taken that as a warning against passing the materials simultaneously through the cannula.

Appellant also contends that modifications proposed as obvious would not have been predictable. Appellant has not provided any evidence to support the argument that a cannula accommodating the simultaneous

passage of screws and a fastener would have been unpredictable. Given that the three references show variations on the same theme, devices through which a variety of implements are passed and surgical procedures are performed, Appellant's argument gives too little weight to the Foley, Ash, and Zdeblick disclosures and to the level of skill reflected in the references.

We conclude that the preponderance of evidence in the record supports the Examiner's conclusion of obviousness. However, because our reliance on the evidence is somewhat different from the Examiner's, we designate the affirmance as a new ground of rejection, pursuant to 37 C.F.R. § 41.50.

Claims 19-26, 30-32, 34-41, and 46-48 have not been argued separately and therefore stand or fall with claim 18, 27, or 33, according to dependency. 37 C.F.R. § 41.37(c)(1)(vii).

This opinion contains a new ground of rejection pursuant to 37 CFR § 41.50(b) (effective September 13, 2004, 69 Fed. Reg. 49960 (August 12, 2004), 1286 Off. Gaz. Pat. Office 21 (September 7, 2004)). 37 CFR § 41.50(b) provides "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review."

37 CFR § 41.50(b) also provides that the Appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

(1) *Reopen prosecution.* Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter reconsidered by the Examiner, in which event the proceeding will be remanded to the Examiner. . . .

(2) *Request rehearing.* Request that the proceeding be reheard under § 41.52 by the Board upon the same record. . . .

Should the Appellant elect to prosecute further before the Examiner pursuant to 37 CFR § 41.50(b)(1), in order to preserve the right to seek review under 35 U.S.C. §§ 141 or 145 with respect to the affirmed rejection, the effective date of the affirmance is deferred until conclusion of the prosecution before the Examiner unless, as a mere incident to the limited prosecution, the affirmed rejection is overcome.

If the Appellant elects prosecution before the Examiner and this does not result in allowance of the application, abandonment or a second appeal, this case should be returned to the Board of Patent Appeals and Interferences for final action on the affirmed rejection, including any timely request for rehearing thereof.

SUMMARY

We affirm the rejection of claims 18-23, 25-27, 30-36, 38-41 and 46-48 under 35 U.S.C. § 103(a) as unpatentable over Foley, Ash, and Zdeblick.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

Appeal 2009-014681
Application 10/689,487

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